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(54) Protective coating for a stent with intermediate radiopaque coating

(57) The invention relates to coated stents and the method of making them. A stent that is substantially radiolucent is at least partially coated with a radiopaque layer that makes the stent visible under X-ray or fluoroscopy. A protective layer is coated on the stent and the radiopaque layer to protect both from scratches, flaking, and galvanic corrosion, and to improve both blood and bio-compatability.

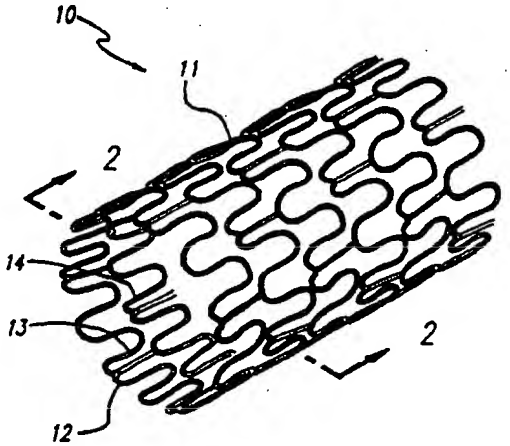

FIG. 1

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Description

The invention relates generally to stents, and more particularly to coatings applied to stents to make the same radiopaque and coatings to protect the stent and the radiopaque layer.

Stents are useful in the treatment of atherosclerotic stenoses in blood vessels and are generally tubular shaped devices which function to hold open a segment of a blood vessel, artery, heart valve or other body lumen. Stents are particularly suitable for use in supporting and holding open a coronary artery after an atherectomy or angioplasty procedure.

Generally, stents are made from a metal alloy, such as stainless steel, and have a hollow tubular shape with an outer wall surface resembling an open lattice configuration. In some prior art stents, the outer wall surface comprises intersecting wires or struts that are expanded beyond the elastic limit thereof to plastically deform and hold open the body lumen in which they are implanted. Other stents are self-expanding and can be in the form of a coil wire that is biased open.

Stents made from stainless steel, for example, are radiolucent, due in part to the intersecting wires having a diameter of about 0.076 mm (0.003 in.) or less. Unless the metal or metal alloy used for making the stent has a high atomic weight and density, it is difficult to visualize in vivo during catheter introduction into the vessel, stent deployment, and post-operative diagnosis.

At least one prior art stent has an increased wire diameter, to approximately 0.102 mm (0.004 in.), in order to make the stent more radiopaque. The disadvantages of a stent having thicker intersecting wires is a more rigid stent that tracks poorly through a tortuous vessel, a stent which is virtually inflexible when tracking on a curved section of vessel, a stent that cannot be implanted easily in a curved section of a vessel, a stent which may not deploy in a uniform cylindrical shape, and a stent with poor hemodynamics. The latter disadvantage, poor hemodynamics, can result in serious medical complications such as thrombosis.

SUMMARY OF THE INVENTION

The disadvantages of the prior art stents are addressed by embodiments of the present invention in which a stent is provided that is sufficiently radiopaque, flexible, has a low profile, is substantially non-thrombogenic, and has a protective layer that will eliminate corrosion while still protecting the stent and other layers from mishandling.

A stent embodying the present invention includes an elongated tubular body that is substantially radiolucent and is formed from, for example, a stainless steel alloy. In order to increase the radiopacity of the stent, without the disadvantages of thicker wires, the stent, or a portion thereof, is coated with a thin radiopaque layer of material having high atomic weight, high density, sufficient surface area and sufficient thickness. With such a coating, the stent is sufficiently radiopaque to be seen with fluoroscopy, yet not so bright as to obstruct the radiopaque dye. This radiopaque layer covers at least a portion of the stent and can be formed from gold, tantalum, platinum, bismuth, iridium, zirconium, iodine, titanium, barium, silver, tin, alloys of these metals, or similar materials.

The radiopaque layer is thin, in one preferred embodiment it is about 1.0 to 50 microns thick. Because the layer is so thin, it is subject to scratching or flaking when the stent is being delivered intraluminally. Accordingly, it is desirable to protect the stent and particularly the radiopaque layer with a more durable protective layer that is resistant to scratching and general mishandling.

Whenever two dissimilar metals are in direct contact, such as a stainless steel stent at least partly covered with a gold radiopaque layer, there is the potential to create the electrochemical reaction that causes galvanic corrosion. The by-product of corrosion (i.e., rust) will not be biocompatible or blood compatible, may cause a toxic response, and may adversely affect adhesion of the radiopaque material. Corrosion will occur if gold and another metal, like stainless steel, are in contact with the same bodily fluid (electrolyte). If the gold coating has any pinholes or has a flaked or scratched-off surface, the underlying stainless steel will be exposed to the same fluid. Therefore, a galvanic reaction (i.e., a battery effect) will occur. The use of a single protective coating covering the entire surface prevents this reaction. This is especially pertinent when the radiopaque layer partially covers the stainless steel stent. The protective layer also prevents galvanic corrosion so that the stent is biocompatible.

In one embodiment of the invention, a separate radiopaque layer can be eliminated by incorporating a radiopaque material, such as barium or titanium oxide, into the protective layer. In this embodiment, the stent is visible under fluoroscopy and it is protected by the protective layer, yet it will have a lower profile since it lacks a separate radiopaque layer.

Other embodiments of the invention include the method of making the stent and of applying a radiopaque layer and a protective layer to it. The radiopaque coating can be applied by dipping, spraying, painting, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, laser welding or fusing, resistance welding, and ion implantation. The protective layer can be applied by dip coating, spray coating, spin coating, plasma deposition, condensation, electrochemically, electrostatically, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, ion implantation, or use of a fluidized bed. The process for applying the radiopaque layer and the protective layer depends upon numerous factors which can include the type of material comprising the layer. These and other advantages of the invention will

become more apparent from the following detailed description thereof and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view depicting a stent having an open lattice structure and covered with both a radiopaque layer and a protective layer.

FIG. 2 is a cross-sectional view of the stent of FIG. 1 taken along lines 2-2, depicting the stent covered by a radiopaque layer and a protective layer over the radiopaque layer.

FIG. 3 is a cross-sectional view of one of the wires of the stent of FIG. 2 taken along lines 3-3, depicting the stent wire being coated with a radiopaque layer and a protective layer.

FIG. 4 is a perspective view of a stent having an open lattice structure and being partially covered by a radiopaque layer and completely covered by a protective layer.

FIG. 5 is a cross-sectional view taken along lines 5-5 of the stent of FIG. 4, depicting a partial radiopaque layer on the stent, covered by a protective layer.

FIG. 6 is a cross-sectional view taken along lines 6-6 of the stent of FIG. 5, depicting a straight portion of a stent wire having a radiopaque layer covered by a protective layer.

FIG. 7 is a cross-sectional view of the stent of FIG. 5 depicting a stent having a protective layer with a radiopaque agent incorporated in the protective layer.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A stent embodying the invention may be intended for either temporary or permanent deployment in a body lumen such as a coronary artery, carotid artery, vessels in the brain, aorta, peripheral arteries and veins, and the like. The stent also can be deployed in the urethra and other body lumens. The stent is used primarily to support the body lumen so that it remains patent and permits the uninterrupted flow of blood or other body fluids. It is important for purposes of delivery, deployment and post-operative diagnosis that the stent be both visible and remain biocompatible. A stent embodying the invention is visible due to a radiopaque layer and it remains biocompatible due its protective layer.

A stent that is made by known etching processes or laser cutting a metal tube, or by winding a metal wire(s), must be sufficiently thick to be radiopaque under X-ray or fluoroscopy in vivo. Generally, current stent designs include an open lattice structure of interwoven wires or struts or coils that are made from stainless steel or other metals or metal alloys that are radiolucent due to a wire thickness or cross-section of about 0.076 mm (0.003 in.) or less. Unless the metal or alloy used for making the stent has high atomic weight and density, it is difficult to visualize the stent in vivo during catheter introduction into the vessel (artery, vein, urethra, etc.), stent deployment, and post-operative diagnosis. Another solution to increase radiopacity of the stent is to increase the strut or wire cross-section to approximately 0.102 mm (0.004 in.), however, this will result in a substantially more rigid stent having poor hemodynamics.

Therefore, coating the stent with a thin layer of material having high atomic weight, high density, sufficient thickness (15 microns or less), and large surface area will have an effect similar to that of thickening the stent. It will make the stent sufficiently radiopaque so that it can be seen, in vivo but not so radiopaque to obstruct the view of radiopaque dye. The coating can be high atomic weight material such as gold, tantalum, platinum, bismuth, iridium, or the like. It also can be lower atomic weight material like zirconium, iodine, titanium, barium, silver, tin, or the like. For the latter-type coatings, a thicker coating may be needed to make the stent sufficiently radiopaque. In either case, a thin coating will allow the stent to remain thin and flexible while maintaining a low stent profile to minimize disruption of blood flow.

On the other hand, thickening the stent or changing the material used for making the stent to a more radiopaque material (i.e., tantalum, gold, etc.) may lead to poor stent performance. A thicker, high profile stent may result in areas of stagnation, turbulence, separation of flow, or other unacceptable fluid dynamics that can promote thrombogenesis. A thicker stent has lower fatigue resistance due to its brittleness. A tantalum stent is brittle and cracks easily. A gold stent will be prohibitively expensive and too ductile. In the thickness range of less than 0.076 mm (0.003 in), a gold stent will not have sufficient strength to support the artery or body lumen. Both will be too radiopaque (stent made from all tantalum or gold) and will obstruct the view of radiopaque dye when it flows through the lumen of the stent. Allowing visualization of the dye flowing through the stent lumen is important for diagnostics. Dye flowing through the stent lumen provides information to the clinician about restenosis, the size of artery, the size of the stent lumen during and after deployment, and the presence of dilation or other important parameters necessary for the care of the patient. This avoids the need for post-insertion and post-operative ultrasound detection procedures necessary to determine the diameters of the stent and vessel lumen. Therefore, a thin radiopaque coating is preferred over a stent made entirely from a highly radiopaque material.

Gold is the preferred radiopaque coating because of its high atomic weight and density, both of which contribute to its radiopacity. In addition, gold is a highly ductile metal and therefore, resists cracking when the stent is stressed during deployment or fatigue after deployment. A thin gold coating (less than 15 microns) is sufficient to absorb enough energy to be opaque when exposed to X-rays. Equivalent radiopacity cannot be

achieved with a stent made from stainless steel or the like unless the stent is at least twice the thickness. Studies have shown that a 2.0 to 3.0 micron gold coating (or other metal) on a 0.058 mm (0.0023 in.) thick 316L stainless steel stent (i.e., where the diameter of the wires or struts is 0.058 mm (0.0023 in.)) is sufficient to elevate the radiopacity to make it equivalent in radiopacity to a 0.102 mm (0.004 in.) thick 316L stent.

When dissimilar metals come in contact, such as the gold radiopaque coating on a stainless steel stent, the potential to initiate galvanic corrosion exists. This phenomenon occurs when two electrochemically dissimilar metals come in contact with each other. In addition, the radiopaque coating may be less biocompatible than the stent material and may induce thrombosis and stenosis after its deployment. Furthermore, the radiopaque coating is prone to scratching and handling mishaps resulting in scratches, a chipped coating, flaking, or other defects. Surface irregularities on these coatings may act as loci for unwanted platelet adhesion or cell lysis.

In order to reduce galvanic corrosion and protect the coating, it is essential to coat the outermost surface of the stent (already coated with a radiopaque coating) with a protective coating. The protective coating provides a protective barrier against mishandling, prevents the electrochemical reaction that causes galvanic corrosion, and is blood and tissue compatible. It is thin and flexible such that it will not crack during stent deployment. It will hide any flaws that are on the surface of the stent and prevent any extraordinary events from occurring. In addition, it has a lower coefficient of friction than most stent materials. A hydrogel layer also can be applied on the inside and/or outside surface of the stent by chemically bonding it to this protective coating. The hydrogel coating then can act as a buffer between the stent and vessel, minimizing vascular injury.

In the preferred embodiment of the invention, as depicted in Figs. 1-2, the stent 10 is a generally cylindrical member having an elongated tubular body 11 with an outer surface 12 and an inner surface 13. When the stent 10 is made from a material that is substantially radiolucent, it is important to increase its radiopacity. In order to increase the visibility of the stent 10, a radiopaque layer 14 is applied to coat all of the stent 10, including the outer surface 12 and the inner surface 13. Typically, the stent 10 will be made from a plurality of intersecting struts or wires 15 that can be formed by known methods as described herein. In this embodiment, the radiopaque layer 14 is applied so that it covers all portions of the struts or the wires 15. As is shown in Fig. 3, the radiopaque layer 14 surrounds the strut 15 so that its radiopacity is ensured. It is preferred that the radiopaque layer 14 have a uniform thickness in the range of 1.0 to 50 microns and, more preferably, in the range of from 1.5 to 10 microns. If the radiopaque layer 14 is too thick, it also may result in the stent 10 being too bright under fluoroscopy and it may interfere with the expansion of the stent. Thus, the thickness of radiopaque layer should be uniform and in the preferred thickness ranges, depending upon such factors as the type of metal in the stent, where it will be implanted, the diameter of the struts 15, and the like.

In keeping with the preferred embodiment, as shown in Figs. 1-3, a protective layer 20 covers and surrounds the radiopaque layer 14 and protects it against scratches, flaking, and other mishandling. Generally, the radiopaque layer 14 will be formed from a relatively soft and malleable metal such as gold, and it is subject to scratching and flaking both before it delivered in the patient and after it is mounted on a catheter and delivered intraluminally. Thus, the protective layer 20 will provide a durable coating to protect the radiopaque layer.

As will almost always be the case, the stent 10 and the radiopaque layer 14 will be formed from dissimilar metals which may initiate the chemical reaction leading to galvanic corrosion. The protective layer 20 completely coats the radiopaque layer 14 thereby eliminating any likelihood of galvanic corrosion.

In another preferred embodiment, as seen in Figs. 4-6, the stent 10 is only partially coated by a partial radiopaque layer 30. Portions of the stent 10 are coated with the partial radiopaque layer 30, while the stent portion 31, which is curved, is not covered by a radiopaque layer. It is noted that the scale of the partial radiopaque layer 30 to the stent struts 33 and the protective layer 34 is somewhat out of proportion for ease of illustration. Typically, as has been demonstrated in experiments, the partial radiopaque layer 30 is applied to straight sections 32 of the struts 33 so that the stent can be expanded without distortion. Many commercial stents have curved sections and curved struts that will twist and deform if the radiopaque layer is applied to the curved section, since the radiopaque layer actually adds some rigidity to the stent. Thus, it is preferred that the partial radiopaque layer 30 be applied to the non-curved struts of the stent. In other stent configurations, it may not matter where the partial radiopaque layer 30 is applied on the stent 10. The primary reason for the radiopaque layer is to enhance the visibility of the stent, but it should not interfere with stent expansion.

In the preferred embodiment shown in Figs. 4-6, the stent 10 is coated by the protective layer 34, which actually covers the stent portion 31 and the partial radiopaque layer 30. The protective layer 34 protects the partial radiopaque layer 30 as described above, and it eliminates the possibility of galvanic corrosion when the stent 10 and the partial radiopaque layer 30 are dissimilar metals.

In an alternative embodiment, the protective layer 34 covers only the partial radiopaque layer 30 and does not cover those portions of the stent 10 where there is no radiopaque coating. Thus, using FIG. 4 as an example, the partial radiopaque layer 30 is applied to straight sections 32 and the protective coating 34 is selectively applied to cover the partial radiopaque layer 30 only.

The radiopaque coating can be made from solid metal (i.e., gold, silver, tin, tantalum, zirconium, platinum, or other metals), ceramic (Zirconia, alumina, zirconium nitrate, titanium nitrite, graphite, pyrolytic carbon, NEDOX, or other ceramics), metal/ceramic-filled particles dispersed in a polymer matrix, or other radiopaque material. The radiopaque coating can be coated anywhere on the stent. It can partially cover the stent (one or more bands, longitudinal continuous or discontinuous band, dots, outside surface only, inside surface only, etc.) or fully cover the stent.

In the preferred method of applying the radiopaque layer 14 or the partial radiopaque layer 30, a radiopaque coating can be applied by dipping, spraying, painting, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, ion implantation, laser welding or fusion, resistance welding, or other methods. The thickness of the radiopaque coating generally is 50 microns or less. The coating can be applied on the inside and/or outside surface of the stent or it can fully encapsulate the stent strut(s).

For instance, a band of gold coating can be placed around the stent at the ends by first completely masking the stent with alkaline or acid-resistant mask material (i.e., the material manufactured under the tradename "MICROSTOP" by Pyramid Chemical Company, polyesters, acrylic, wax, etc.). The type of mask material depends on what coating process is to be used. After the stent has been masked, the mask is removed preferentially from the stent surface, using a laser, sandblaster, or other appropriate method. Any pattern can be made by selectively removing mask material. The exposed surface (non-masked areas) then can be coated with radiopaque material by the above-described methods (i.e., electroplating). Other masking techniques also are possible (i.e., physical, chemical, or mechanical). In addition, prefabricated gold markers also can be laser-fused or resistance-welded to the stent at any specific locations. Further details of applying a radiopaque layer to a stent are found in co-pending European Patent Application No. 95302708.3.

In the preferred method of applying the protective layer 30,34, the biocompatible and blood-compatible protective layer can be polymeric, "PARYLAST", polymethylene, metallic, or ceramic. A polymeric layer (i.e., parylene, polycarbonateurethane copolymer, silicone rubber, hydrogels, polyvinyl alcohol, polyvinyl acetate, polycapralactone, urethanes, PHEMA-Acrylic, etc.) can be applied onto the radiopaque-coated stent by dip-coating, spray-coating, spin-coating, plasma deposition, condensation, electrochemically, electrostatically, or other suitable methods. "PARYLAST" is a preferred protective coating and is distributed by Advanced Surface Technology Corp. A metallic coating (i.e., titanium and tantalum) can be applied by electroplating, evaporation, plasma-vapor deposition, cathodic-arc deposition, sputtering, ion implantation, electrostatically, electrochemically, a combination of the above, or the like. A ceramic coating (i.e., zirconium nitrite, pyrolytic carbon, graphite, a material sold under the tradename "NEDOX" by the General Magnaplate Corporation, and titanium nitrite) can be applied by the use of a fluidized bed, spraying, plasma-vapor deposition, evaporation, sputtering, electrochemically, electrostatically, a combination of the above, or the like. The thickness of the protective layer preferably is from .01 to 25 microns.

In an alternative preferred embodiment, as shown in Fig. 7, the stent 10 is at least partially covered by a protective coating 40 which is itself radiopaque. The protective coating 40 is loaded with radiopaque agents such as barium, titanium oxide, and the like. Further, multiple layers of the protective layer can be applied to the stent where the first layers are loaded with radiopaque agents while the outermost protective layer is not loaded with a radiopaque agent.

In another embodiment, not shown in the drawings, the protective layer is first applied to cover the stent and the radiopaque layer is applied to partially or completely cover the protective layer. In this embodiment, the radiopaque layer is scratch resistant and biocompatible.

A protective layer has been described herein as a mechanical barrier which protects against mishandling, electrochemical reaction that causes galvanic corrosion, and against adverse blood and tissue response. It also is important that the protective layer form a conformal coating that will adhere to the stent surface. When there is no adhesion, any stretching and straining of the stent may lead to a rupture of the protective layer, resulting in folds at the strained areas (like elephant skin folds) which may lead to a penetration of blood and tissue causing an adverse response, or causing galvanic corrosion.

Thus, with respect to all of the protective layers disclosed herein, the process to improve adhesion between the protective coating and the substrate (the radiopaque layer) is desired. One such process is to deposit a thin intermediate layer or layers from the silane group or to plasma deposit a polymer from a gaseous organic such a methane, xylene or gases from the silane or titanate groups. A preferred method is to deposit "PARYLAST," a coating which incorporates the deposition of an intermediary followed by parylene C in the same processing chamber. In addition to an intermediary layer, improved adhesion can be attained by reducing the thickness of the protective coating. Thinner coatings tend to be more flexible, especially when the material has a glass transition temperature above room temperature. Thus, thinner coatings adhere better.

Thus, a preferred method is to deposit "PARYLAST," a parylene C coating, which incorporates the addition of an intermediary in the same process chamber.

Another method for improving the adhesion between the protective layer and the radiopaque layer is by acid treatment, sandblasting, or similar methods.

These methods allow a mechanical interlocking between the substrate and the protective layer.

"PARYLAST" can be coated at different thicknesses that can vary from 0.013 mm to 0:0025 mm (.00005 in. to .0001 in.). It is preferred that the thickness of the "PARYLAST" be at least 0.0025 mm (0.0001 in.) in order to minimize the potential for pinhole formation, while maintaining the optimum flexibility (thicker coatings may be too rigid and affect stent expansion). The degree of texture on the substrate may vary from 1 to 250 micron average pore sizes. It is preferred that the substrate have a 1-6 micron average pore size. At larger pore sizes, the textured surface is retained on the coated surface after parylene C or a "PARYLAST" treatment.

After the protective layer is applied on the surface, other coatings that may be more blood compatible also can be applied. For example, coatings such as the one sold under the tradename "DUROFLO," manufactured by the Bentley Company, and the one sold under the tradename "PHOTOLINK HYDROGEL," manufactured by the BSI Corporation, and the one sold under the tradename "PHOTOLINK HEPARIN," also manufactured by the BSI Corporation, or similar coatings, can enhance the blood compatibility of the stent.

While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the scope of the invention. Thus, it should be understood that various changes in form, and detail, and application of the present invention may be made without departing from the scope of this invention.

Claims

1. A stent (10) for implanting in a body lumen, comprising:

   an elongated tubular body (11) being substantially radiolucent;
   a radiopaque layer (14) covering at least a portion of the elongated tubular body (11);
   a protective layer (20) covering the elongated tubular body (11) and radiopaque layer (14) to reduce the likelihood of galvanic corrosion between the elongated tubular body and the radiopaque layer and to protect the layers from mishandling.

2. The stent (10) of claim 1, wherein the elongated tubular body (11) is formed from a metallic material taken from the group of metallic materials including stainless steel, nickel-titanium, tantalum, and titanium.

3. The stent (10) of claim 1 or claim 2, wherein the elongated tubular body (11) has a wall surface made up of a plurality of struts (15) each having a diameter of less than about 0.102 mm (0.004 in.).

4. The stent (10) of any preceding claim, wherein the protective layer (20) has a thickness in the range of approximately .01 to 25 microns.

5. The stent (10) of claim 4, wherein the thickness of the protective layer (20) can vary in thickness on the elongated tubular body (11) from about .01 to 25 microns and on the radiopaque layer (14) from about 1.0 to 50 microns.

6. The stent (10) of any preceding claim, wherein the protective layer is biocompatible and blood compatible.

7. The stent (10) of any preceding claim, wherein the protective layer is formed from a polymeric, metallic or ceramic material.

8. The stent (10) of claim 7, wherein the protective layer (20) is formed from the polymeric material taken from the group of polymeric materials including "PARYLAST," parylene, polymethylene, polycarbonate-urethane copolymer, silicone rubber, hydrogels, polyvinyl alcohol, polyvinyl acetate, polycapralactone, urethanes, and PHEMA-Acrylic.

9. The stent (10) of claim 7, wherein the protective layer (20) is formed from the metallic material taken from the group of metallic materials including titanium, tantalum, and titanium-alloy.

10. The stent (10) of claim 7, wherein the protective layer (20) is formed from the ceramic material taken form the group of ceramic materials including zirconium nitrite, graphite, pyrolytic carbon, "NEDOX" and titanium nitrite.

11. The stent (10) of claim 1, wherein a second protective coating covers the protective coating (20) to provide further protection against the electrochemical reaction that causes galvanic corrosion.

12. A method for protecting a stent from the electrochemical reaction that causes galvanic corrosion, the method comprising:

    providing an elongated tubular body (11) being substantially radiolucent;
    applying a radiopaque layer (14) on at least a portion of the elongated tubular body; and
    applying a protective layer (20) on the elongated tubular body (11) and the radiopaque layer (14), the protective layer (20) covering all of the radiopaque layer and that portion of the elongated tubular body not covered by the radiopaque layer.

13. The method of claim 12, wherein the method for applying the radiopaque layer (14) includes dipping, painting, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, laser welding or fusion, resistance welding or ion implantation.

14. The method of claim 12 or claim 13, wherein the method for applying the protective layer (20) includes dipping, spraying, spin coating, plasma deposition, condensation, electrostatically, electrochemically, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, ion implantation, or use of a fluidized bed.

15. A stent (10) for implanting in a body lumen, comprising:

an elongated tubular body (11) being substantially radiolucent; and
a protective layer (20) covering the elongated tubular body (11), the protective layer having radiopaque means for increasing visibility under fluoroscopy, the protective layer (20) also protecting against the electrochemical reaction leading to galvanic corrosion.

16. The stent (10) of claim 15, wherein the protective layer (20) has a thickness in the range of .01 to 25 microns.

17. The stent (10) of claim 15, wherein the protective layer (20) is formed from a polymer, a metal, or a ceramic material.

18. The stent (10) of claim 17, wherein the radiopaque means includes loading the protective layer material with a radiopaque agent taken from the group of radiopaque agents including barium, titanium oxide, gold, or other metallic powders or particles.

19. The stent of any of claims 15-18, wherein the protective layer having radiopaque means for increasing visibility under fluoroscopy is covered by a second protective layer.

20. A stent (10) for implanting in a body lumen, comprising:

an elongated tubular body being substantially radiolucent;
a protective layer (20) covering the elongated tubular body; and
a radiopaque layer (30) covering at least a portion of the protective layer so that the stent (10) is visible under fluoroscopic x-ray, the protective layer (34) reducing the likelihood of galvanic corrosion between the radiopaque layer and the elongated tubular body.

21. A stent (10) for implanting in a body lumen, comprising:

an elongated tubular body (11) being substantially radiolucent;
a radiopaque layer (30) covering at least a portion of the elongated tubular body; and
a protective layer (34) covering at least a portion of the elongated tubular body (11) to reduce the likelihood of galvanic corrosion between the elongated tubular body and the radiopaque layer and wherein the protective layer is biocompatible and blood compatible.

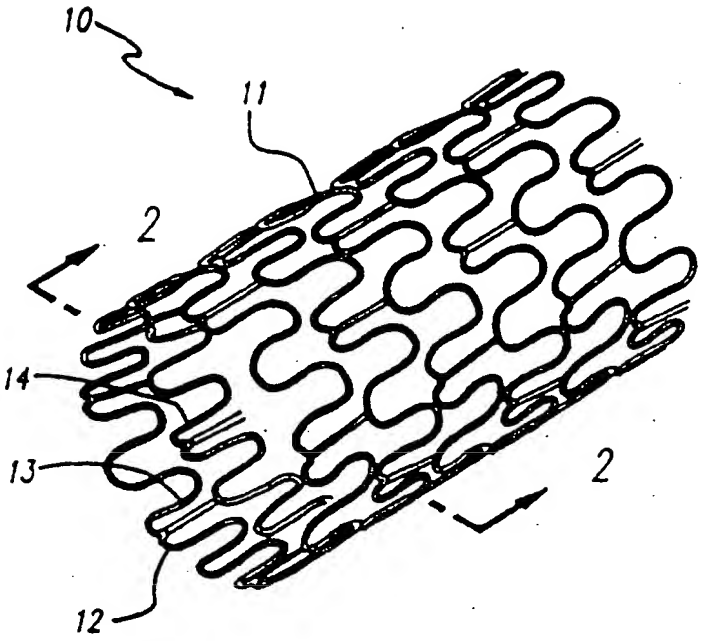


FIG. 1

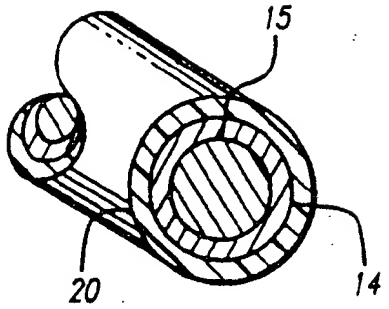


FIG. 3

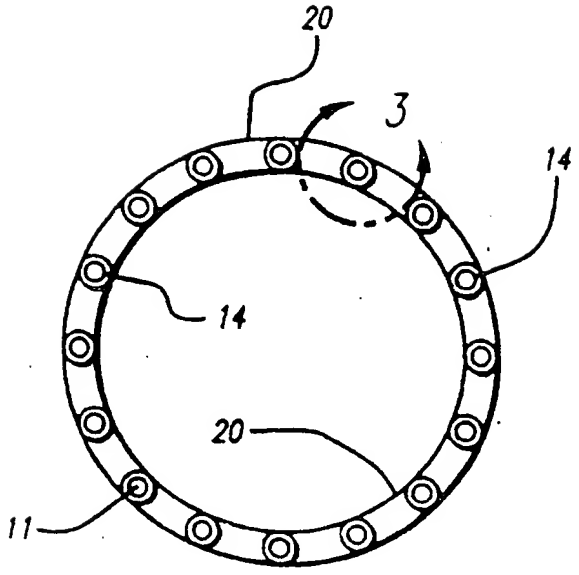
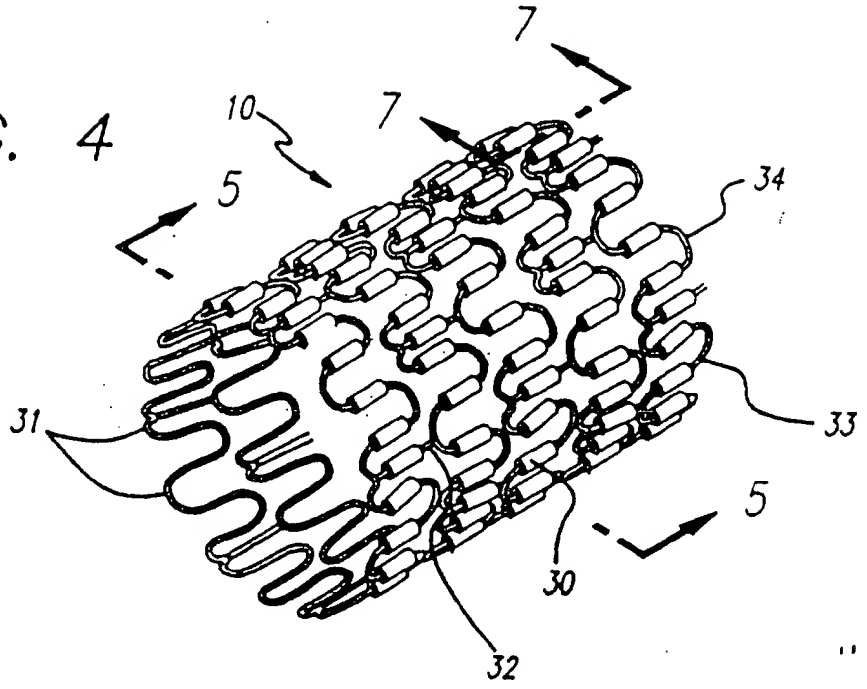


FIG. 2

FIG. 4



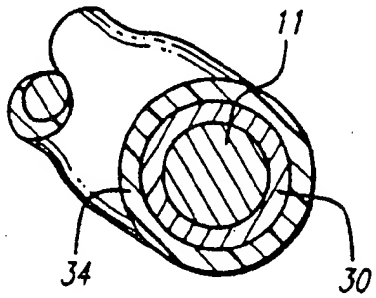


FIG. 6

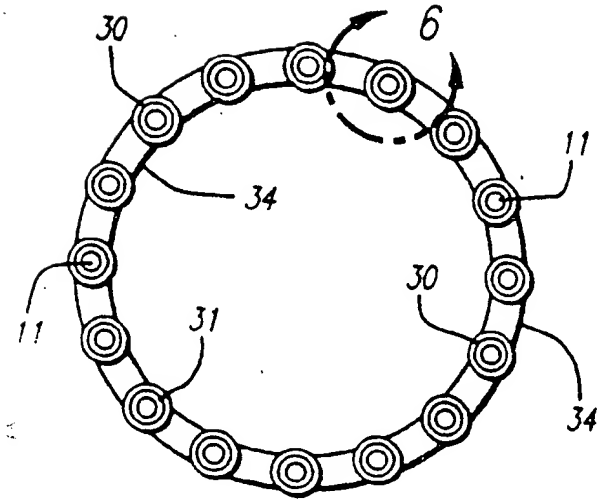


FIG. 5

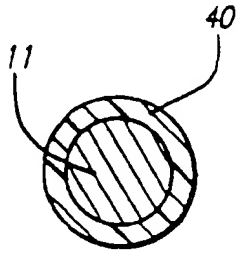


FIG. 7

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(54) Protective coating for a stent with intermediate radiopaque coating

(57) The invention relates to coated stents and the method of making them. A stent that is substantially radiolucent is at least partially coated with a radiopaque layer that makes the stent visible under X-ray or fluoroscopy. A protective layer is coated on the stent and the radiopaque layer to protect both from scratches, flaking, and galvanic corrosion, and to improve both blood and bio-compatability.

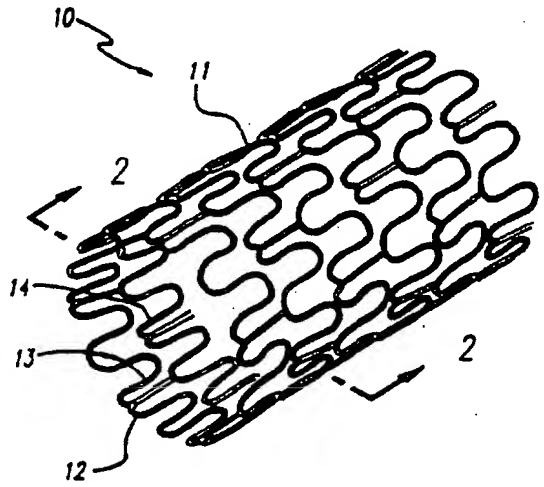

FIG. 1

EP 0 824 900 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 30 9057

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y A	EP 0 679 373 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 2 November 1995 * the whole document *	1-8, 11-14,21 15,20	A61F2/06 A61L27/00
Y	EP 0 679 372 A (ADVANCED CARDIOVASCULAR SYSTEMS,INC.) 2 November 1995 * the whole document *	1-8, 11-14,21	
A	EP 0 448 016 A (UNION CARBIDE CHEMICALS AND PLASTICS COMPANY, INC.) 25 September 1991		
A	WO 96 24393 A (SURFACE SOLUTIONS LABORATORIES, INC.) 15 August 1996		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	27 July 1998	Smith, C

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